K100524 P1/3

5.1

510(k) Summary

MAY 2 4 2010

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

Submitter: Pierre Landau, PhD
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Contact Person: Same as submitter

Date of Summary: May 1, 2009

Trade Name: Polytel® APT (Access Point Terminal)

Common Name: Physiological Measurement Tramitter and Receiver

Classification: no: DRG

A. Predicate Devices:
The Polytel® APT is substantially equivalent to the following predicate devices:

510(k) number: K041816
Device Name: RTX3320 Wireless Telehealth Gateway
Applicant: RTX Healthcare

510(k) number: K080538
Device Name: IDEAL LIFE Pod™, Model ILP 0001
Applicant: Ideal Life

B. Device Description:
The Polytel® APT device performs transmission of physiological patient information to and from wireless patient monitors and a remote data server healthcare facility over an encrypted dialup Internet connection. The APT, with its built-in telephone modem, transmits data over the public switched telephone network and the dial-up Internet.

The APT is contained in a small plastic unit, containing two standard telephone jacks for connection to standard phone outlets, a 5V power input jack for connection to an AC adapter, and four indicator lights. The indicator lights are used to show the reception of a measurement from a transmitting device, to show when the telephone line is in use, and to indicate if there has been an error (delay) in transmission.

Two server-side components are involved in the operation of the APT, the first providing a centralized configuration database, the second providing for data collection and translation to a standard protocol.

The APT device is not used directly on a patient, nor attached electrically to any device that is used directly on a patient, and poses no significant risk to the patient or other people within the patient's home.

C. Intended use and indications for use:

The Polytel® APT receives data wirelessly from compatible devices to transmit over the Internet or common telephone lines. The APT is an optional accessory to other Polytel® devices, including the various GMA (glucose meter accessory) models, blood pressure meter, weight scale and spot-check SpO_2. The APT is intended to aid people at home and health care professionals to review and evaluate historical blood glucose, weight and blood pressure test results, to support effective health care management.

The APT does not measure, interpret, or make any decisions with respect to any of the data it transports. All patient medical diagnosis and treatment are to be performed under the supervision and oversight of appropriate healthcare professional. This device is not intended as a substitute for medical care.

Any device certified by Polymap Wireless as compatible can use the Polytel® APT to forward its data.

The device is not intended for emergency calls, and may not be used to send any real-time alarms or time-critical data. The device is not intended for use in systems set up for patients who need direct medical supervision or who might need emergency intervention.

The APT and its compatible devices must be used in conjunction with a subscription to a compatible monitoring service. The monitoring service may distribute the APT to the patient; alternatively, the patient may acquire the APT and other compatible devices and subscribe to a compatible service.

A list of compatible devices and services will be available on the Polymap Wireless website.

D. Substantial Equivalence Summary:
The Polytel APT has the same fundamental scientific technology and intended use as the predicate devices (K041816, K080538).

E. Technological Characteristics:
The Polytel APT has technological characteristics that are very similar to those of the predicate devices, as all use Bluetooth technology and dial-up modems. All of these

devices are line-powered, and each device uses the same frequency band of 2.402-2.480 GHz.

F. Testing:
The testing consisted of three types: bench testing using Polymap procedures and specifications; field testing under actual use conditions, and performance standards testing. The results were acceptable.

G. Conclusions
This pre-market submission has demonstrated substantial equivalence, as defined and understood in sections 513(0)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 2 4 2010

Polymap Wireless LLC
c/o Mr. Pierre Landau, Ph.D.
President
310 S. Williams Blvd. Ste. 350
Tucson, AZ 85711

Re: K100524
Device Name: Polytel® APT (Access Point Terminal)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (Two)
Product Code: DRG
Dated: February 10, 2010
Received: February 24, 2010

Dear Mr. Landau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100524

Device Name: Polytel® APT

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device

510(k) _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100524